

Notice of Allowability

Application No.

10/048,191

Examiner

Mary E. Mosher, Ph.D.

Applicant(s)

CHIEN ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
2. ☒ The allowed claim(s) is/are 1-15.
3. ☒ The drawings filed on 25 January 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: ____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. ____.
 - (b) ☐ including changes required by the proposed drawing correction filed ____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. ____. |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. <u>5/28/03</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input checked="" type="checkbox"/> Other <i>Post-allowance</i> correspondence. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Alisa Harbin (33895) on December 11, 2003.

The specification and the claims have been amended as indicated on the attached pages.

The following is an examiner's statement of reasons for allowance:

Cardoso et al (Journal of Medical Virology 55:28-34, 1998) is cited as the closest prior art. Cardoso teaches human monoclonal antibodies directed against HCV envelope proteins, and use of the monoclonal antibodies together with anti-human antibodies in an immunofluorescence assay, see Figure 5. However, Cardoso failed to detect any kind of complex in samples containing virus, only detecting a signal in cells engineered to express the HCV proteins. Therefore, Cardoso fails to teach or suggest use of the antibodies for samples suspected of containing HCV virus, or packaging the antibodies together with printed material.

Patents such as Persson et al (WO 97/40176) suggest an assay for detecting HCV env antigen or virions using anti-env monoclonal antibodies, but do not teach or suggest using an anti-human antibody in addition. Chien et al (WO 99/15898) teach an antigen-capture assay for HCV antigen using anti-human antibodies, but do not teach or

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suggest using an anti-env monoclonal antibody in addition. Reesink et al (Dev. Biol. Stand. 81:77-84, 1993) and Deleersnyder et al (Journal of Virology 71:697-704, 1997) indicate that those skilled in the art believed that detection of HCV antigens was difficult, because of low levels of HCV particles in samples. The review by Pawlotsky (Journal of Hepatology 31 (Suppl.1): 71-79, 1999) indicated knowledge of an assay for detecting HCV core antigen, but that the assay was less sensitive than other existing assays. Aoyagi et al (J. Clin. Microbiol. 37:1802-1808, 1999) teach a more sensitive assay for detecting HCV core antigen, but teach destruction of the endogenous bound human antibodies with heat and detergent before assay, not detection with added anti-human antibodies. Taken together, the art as a whole does not provide adequate motivation to combine the disparate elements of anti-human antibodies and anti-env monoclonal antibodies in a diagnostic assay for detecting hepatitis C virus in a suspect sample, with reasonable expectation of success.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926 until approximately 1/8/2004, 571-272-0906 afterwards. The examiner can normally be reached on M-T and alternate F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027 until approximately 1/26/2004, 571-272-0902 thereafter. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

12/11/03


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600-1600

Amendment to the claims

1. (Amended) A method for detecting hepatitis C virus in a biological sample comprising the steps of:

contacting said a biological sample suspected of containing hepatitis C virus with an anti human antibody and at least one monoclonal anti-hepatitis C virus envelope protein antibody under conditions that allow an immunologic reaction between said antibodies and said sample; and

detecting the presence of immune complexes of said antibodies and said envelope protein, wherein detecting said immune complexes indicates the presence of hepatitis C virus.

2. The method of claim 1 wherein said anti-human antibody is attached to a solid phase.

3. The method of claim 2 wherein said solid phase is selected from the group consisting of microtiter plates, paramagnetic particles, and paramagnetic beads.

4. (Amended) The method of claim 1 wherein said monoclonal antibody reacts with an epitope selected from the group consisting of an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an e1 conformational epitope, an e1 linear epitope, and an e1 linear neutralizing epitope.

5. (Amended) The method of claim 1 wherein said at least one monoclonal antibody reacts with an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an e1 conformational epitope, an e1 linear epitope, an e1 linear neutralizing epitope, or a combination thereof.

6. The method of claim 1 wherein said monoclonal antibody is detectably labeled.

7. The method of claim 1 wherein said anti-human antibody is contacted with a polyclonal anti-hepatitis C virus envelope protein antibody prior to contact with a biological sample.

8. (Amended) A method for detecting hepatitis C virus in a biological sample comprising:

contacting an anti-human antibody attached to a solid phase with a polyclonal anti hepatitis C virus envelope protein antibody;

contacting said a biological sample suspected of containing hepatitis C virus to said polyclonal antibody;

contacting said sample with at least one detectably-labeled, monoclonal anti-hepatitis C virus envelope protein antibody under conditions that allow an immunologic reaction between said antibodies and said sample; and

detecting the presence of immune complexes of said antibodies and said envelope protein, wherein detecting said immune complexes indicates the presence of hepatitis C virus.

9. A method of screening blood components or blood for hepatitis C virus prior to the use of such blood or blood component to prepare blood products comprising:

reacting a body component from a potential donor with an anti-human antibody and at least one monoclonal anti-hepatitis C virus envelope protein antibody under conditions that allow an immunologic reaction between said antibodies and said body component;

detecting the presence of immune complexes formed between said antibodies and hepatitis-C virus envelope proteins; and

discarding any blood or blood component from said donor if said complexes are detected.

10. A kit for detecting hepatitis C virus in a biological sample comprising:

an anti-human antibody;
at least one monoclonal anti hepatitis C virus envelope protein antibody;
control standards; and
instructions for use of the kit components.

11. The kit of claim 10 further comprising a polyclonal anti-hepatitis C virus envelope protein antibody.

12. The kit of claim 10 wherein said anti-human antibody is attached to a solid phase.

13. (Amended) The kit of claim 10 wherein said monoclonal antibody reacts with an epitope selected from the group consisting of an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an e1 conformational epitope, an e1 linear epitope, and an e1 linear neutralizing epitope.

14. (Amended) The kit of claim 10 comprising a plurality of monoclonal antibodies which react with an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an e1 conformational epitope, an e1 linear epitope, an e1 linear neutralizing epitope, or a combination thereof.

15. The kit of claim 10 wherein said monoclonal antibody is detectably labeled.

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Amendment to the specification

Insert on page 1 above "Field of the invention":

This is a U.S. national application of PCT/US00/20214, filed 25 July 2000, which claims benefit of provisional application 60/146,079, filed 28 July 1999.